

## CLAIMS:

1. A pharmaceutical preparation suitable for use in the eye, which comprises:
  - (i) a pharmaceutically acceptable carrier suitable for use in the eye;
  - 5 (ii) one or more ingredients selected from factors and agents that promote any one or more of survival, health, cell attachment and normal differentiation of ocular surface epithelial cells and optionally factors and agents that prevent squamous metaplasia;
  - (iii) one or more agents capable of altering the fluid properties of a tear film including at least one agent capable of establishing and/or maintaining a stable tear film and optionally one or  
10 more agents selected from ophthalmological lubricating agents, viscosity enhancing agents and agents capable of reducing tear film evaporation;the factors and agents in components (ii) and (iii) being synthetic or recombinant or licensed for pharmaceutical use.
- 15 2. A pharmaceutical preparation as claimed in claim 1, further comprising:
  - (iv) one or more agents suitable for use in the treatment or prophylaxis of an ocular surface disease, disorder or damage.
- 20 3. A pharmaceutical preparation as claimed in claim 1 or claim 2, further comprising:
  - (v) one or more ingredients selected from factors and agents that promote any one or more of survival and maintenance of stem cell characteristics, growth of ocular surface stem cells, and survival, maintenance and differentiation of stem cell offspring *in vitro* or *in vivo*, the factors and agents being synthetic or recombinant or licensed for pharmaceutical use.
- 25 4. A pharmaceutical preparation as claimed in claim 2 or claim 3, wherein the one or more of the agents (iv) suitable for use in the treatment or prophylaxis of an ocular surface disease, disorder or damage is selected from:  
mydriatics agents, steroids, mucolytic agents, inhibitors of angiogenesis, attachment factors, antifibrotic agents, antimicrobial agents, anti-glaucoma agents, and agents that reduce the  
30 accumulation of toxic by-products of cell metabolism.
5. A pharmaceutical preparation as claimed in any one of claims 1 to 4, wherein component (i) comprises one or more agent selected from:  
purified water for eye drops, cream bases for ophthalmological compositions, gel bases for  
35 ophthalmological compositions and ointment bases for ophthalmological compositions.

6. A pharmaceutical preparation as claimed in any one of claims 1 to 5, wherein component (ii) comprises one or more agent selected from:

agents that provide a metabolisable source of carbon, amino acids, growth factors, vitamins, antioxidants, mucin substitutes, bulk ions, trace elements, proteins, hormones, protease inhibitors, and anti-microbial agents.

7. A pharmaceutical preparation as claimed in any one of claims 1 to 6, wherein an agent capable of establishing and/or maintaining a stable tear film is selected from:

lipids, lipoproteins and meibomian gland secretions, and synthetic analogues thereof.

8. A pharmaceutical preparation as claimed in any one of claims 1 to 7, wherein component (iii) comprises an ophthalmological lubricating agent, a viscosity enhancing agent or an agent capable of reducing tear film evaporation selected from:

hypromellose, Semisynthetic cellulose derivatives, methylcellulose, hydroxypropylmethylcellulose, carbomer, carmellose, polyvinyl alcohol, polyacrylic acid, povidone, dextran solutions, hyaluronic acid and chondroitin sulphate.

9. A pharmaceutical preparation as claimed in any one of claims 1 to 8, which does not contain benzalkonium chloride.

10. A pharmaceutical preparation as claim in any one of claims 1 to 9, which comprises an anti-microbial agent selected from:

lactoferrin, lysozyme, defensin and sIgA;  
so that the preparation may be kept at 4 degrees Celsius for up to one month without microbial contamination.

11. A pharmaceutical preparation according to any one of claims 1 to 10, which has a pH in the range of from 6.6 to 8.0.

12. A pharmaceutical preparation as claimed in any one of claims 1 to 11, which is in the form of a solution for use as eye drops.

13. A pharmaceutical preparation as claimed in any one of claims 1 to 11, which is in the form of a cream, ointment or gel.

14. A pharmaceutical preparation as claimed in claim 12, wherein said solution for use as eye drops has an osmolarity in the range of from 290 mOsm to 320mOsm.

15. A pharmaceutical preparation as claimed in claim 12 or claim 14, wherein said solution for use as eye drops has a surface tension in the range of from 40 dyne/cm to 80 dyne/cm.
- 5 16. A pharmaceutical preparation as claimed in claim 12, claim 14 or claim 15, wherein said solution for use as eye drops has a viscosity in the range of from 5 cps to 50 cps.
17. A pharmaceutical preparation as claimed in any one of claims 1 to 16 in a single dose container.
- 10 18. A pharmaceutical preparation as claimed in any one of claims 1 to 17 for use as a medicament.
19. A pharmaceutical preparation as claimed in claim 18, wherein said medicament is  
15 for the treatment of an ocular surface disorder.
20. A pharmaceutical preparation as claimed in claim 19, wherein said ocular surface disorder is selected from:  
dry eye, severely dry eye, scarring, ocular pemphigoid, persistent epithelial defect, acute  
20 ocular surface disease, chronic ocular surface disease, infection or inflammation of the eye, neoplastic conditions of the eye and trauma to the eye.
21. Use of a pharmaceutical preparation as claimed in any one of claims 1 to 17 for the manufacture of a medicament for the treatment of a condition defined in claim 19 or claim 20.
- 25 22. A method of treating an ocular surface disorder in a subject in need of such treatment comprising administering a therapeutically effective amount of a pharmaceutical preparation as claimed in any one of claims 1 to 17.
- 30 23. A method as claimed in claim 22, wherein the ocular surface disorder is as defined in claim 20.
24. A method as claimed in claim 22 or claim 23, wherein the subject is a mammal.
- 35 25. A method as claimed in claim 24, wherein the mammal is a human.

26. Use of a pharmaceutical preparation according to any of one claims 1 to 17 as a pharmaceutical vehicle or carrier for an ophthalmological pharmaceutical composition.

27. A pharmaceutical preparation as described herein with reference to any one or more  
5 of the examples.